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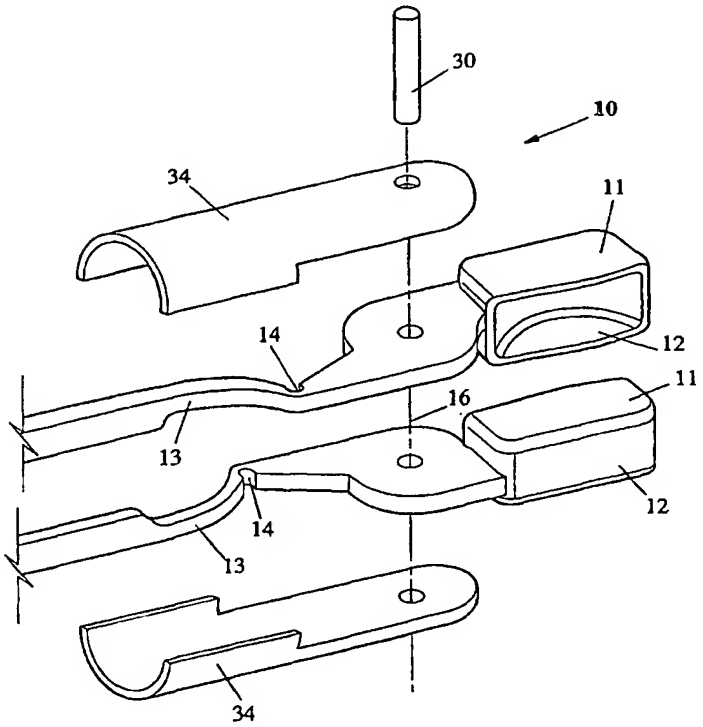
(54) Title: DISPOSABLE ENDOSCOPIC BIOPSY DEVICE

(57) Abstract

There is disclosed a biopsy head (10) including biopsy forceps or jaws (11) integrally connected to actuating members (13) by means of an integral joint (14) thereby avoiding the need for a hinge and allowing for an instrument which may be economically and simply manufactured, thereby suited for disposable application.



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DISPOSABLE ENDOSCOPIC BIOPSY DEVICE

Field of the Invention

The present invention relates to biopsy forceps for attachment to an endoscopic biopsy device and more particularly to forceps that are inexpensive to produce and therefore disposable after one use.

Background Art

The diagnosis of several diseases often involves the removal of small samples of tissue from a part of the living body for microscopic examination, a procedure known as biopsy. Endoscopic biopsy involves the removal of mucosal tissue or biopsy of neoplastic growths found in parts of the body accessible to an endoscope such as the gastro-intestinal tract or other parts of the body.

The endoscope is inserted into the body of an individual and when the biopsy head is adjacent an area of tissue to be sampled, it is actuated to bring two biopsy cups together. The cups act together to cut a small sample from the adjacent tissue.

The biopsy heads currently in use are usually formed of stainless steel and comprise a number of different parts which are usually hingedly joined together. As a result conventionally employed biopsy heads are expensive to make and therefore designed to be re-used many times. While the heads can be sterilised by autoclaving there is still a chance of cross contamination from one patient to another, and in particular there is justifiable concern among many that viruses such as Hepatitis B and HIV may be spread from one patient to another. It is therefore desirable to move to a disposable alternative.

The present invention relates to a design for a biopsy forceps head which because its components need not be hingedly connected and because it may be made from a suitable synthetic plastics material is inexpensive to produce and so disposable after one use only.

Disclosure of the Invention

The present invention relates to an endoscopic biopsy device, the biopsy device including two individual members or "jaws" which are pivoted about a common axis thereby forming a forceps, each jaw including a tissue capturing means, such as a biopsy cup having a concave body, and an actuator member, the actuator member attaching to a jaw at a flexible joint.

In one embodiment each actuator member is preferably connected, at the end distal the biopsy cups, to actuator means such as an endoscope cable, which can be manipulated by a doctor performing the biopsy. Manipulation of the actuator means causes movement of the actuator members which in turn leads to flexion or extension of the flexible joint members causing the biopsy cups to move between their open and closed position.

In a still further embodiment the biopsy head is formed from a synthetic plastics material such as polyamide nylon.

In a preferred embodiment, the individual members are held together relative one another at the pivotal point by means of a pin or a screw made from a suitable plastics or any other material and adapted such that the biopsy heads can articulate relative one another upon actuation.

Preferably there is a space between the biopsy cups at the end closest the pivotal point, the space allowing the escape of fluids or excess tissue from between the cups. If the space is not provided an air lock may result preventing a sufficient amount of tissue for sampling from being caught between the cups. There may also be cases in which the biopsy cups are prevented from closing due to tissue being caught between the cups on the side opposite to the opposed cutting surface.

Consequently, according to the present invention there is provided a biopsy device comprising :

a pair of biopsy jaws, each of said jaws having a tissue capturing means at a first end and a flexible joint at a second end, pivot engagement means being located between said first and second ends;

a pair of actuator members each coupled to one of said joints;

an actuator housing surrounding said actuator members;

a pivot means interconnecting said actuator housing and said pair of jaws;

each said biopsy jaw, including said flexible joint, being formed integrally with said actuator member.

According to a further aspect of the invention there is provided a biopsy jaw forming one half of a pair of forceps for use in a biopsy device, said jaw including a flexible joint integrally connected to an actuator member.

It will be realised that, because each of the biopsy jaws, including tissue capturing means such as a cup, are attached to the actuator member by way of a flexible joint member, there is no requirement for the individual components to be hingedly connected. This has the advantage that each jaw, including a hinge, can be formed integrally with an actuator member, the moulded individual members are identical and can be pinned together at the pivotal point such that the edges of the biopsy cups may be brought into cutting opposition. The fact that the individual members can be moulded in one piece results in decreased production costs making it feasible to use the biopsy heads for only one procedure on a patient before their disposal.

Brief Description of the Drawings

Figure 1 is a view of the components of a biopsy head according to the present invention when disassembled.

Figure 2 is an exploded view of a biopsy head according to the present invention with components orientated in the positions they assume when assembled.

Figure 3 is a side elevational view of a biopsy head according to the present invention with the biopsy cups in a closed position.

Figure 4 is a side elevational view of the biopsy head of Figure 3 with the biopsy cups in an open position.

Figure 5 is a view of an endoscopy device incorporating a biopsy head according to the present invention.

Best Mode of Carrying out the Invention

The following description is given by way of example only of one preferred embodiment of the invention.

With reference to Figure 1, which shows a disassembled biopsy device or "head" according to the present invention, it is seen that there are provide two identical individual members 11 each being a "jaw" of the biopsy head.

When assembled, jaws 11 are pivotally connected by pin 30 between flanges 32 of actuator housing 34. Pin 34 is kept in place, for example by heat welding it at either end to actuator housing 34. With reference to Figure 2, which is an exploded view of the biopsy head when assembled it is seen that jaws 11 are identical individual members. Each jaw 11 includes a biopsy cup 12 connected to an actuator member 13. Each actuator member 13 is joined to an integral flexible joint 14 and is housed within actuator housing 34. The individual members 11 are pivotable, by means of pin 30 about each other along an axis indicated by centre line 16. That is, the individual members 11 are pivotable about a point between the integral flexible joints 14 and the biopsy cups 12.

It has been found that actuator jaws 11 and pivot pin 30 may be conveniently made from a polyamide nylon although other types of nylon and synthetic materials would also be appropriate. The housing 34 is preferably made of polycarbonate or some synthetic material harder than nylon, or even of metal, in order that it support pivot pin 30 without undue deformation. Significantly, it is most convenient to form each jaw 11 and actuator 13 in a single die injection or moulding process. It will be noted that flexible joints 14 are formed without recourse to the hinge structures which are present in prior art biopsy heads.

A user of biopsy head 10 is able to manipulate actuator members 13 relative to actuator housing 34 such that the integral flexible joints 14 flex. Flexing of both joints 14, by pushing actuator members 13 towards pivot axis 16 results in articulation of the biopsy cups 12 away from each other and into an open configuration. This procedure is readily appreciable from inspection of Figures 3 and 4.

The user can further manipulate members 13, by pulling them away from pivot axis 16 such that the joints 14 extend which in turn brings the biopsy cups 12 into a closed configuration.

Each biopsy cup 12, which operates as a tissue capturing means, has a concave body 17 that has a free edge 18. Free edges 18 are adapted to abut against one another, at least at end 19 of the biopsy cups 12 distal pivotal point 16 when the biopsy head is in the closed position as depicted in Figure 3.

The abutting edges 18 are sufficiently rigid and sharp that in use a small sample of tissue can be cut from the underlying tissue when caught between the edges 19.

The edges 18 should lie in sufficient proximity around the periphery of the biopsy cups 12 when they are in the closed position such that stray tissue will not find its way into the biopsy cups 12 as the biopsy head 10 is placed into the body of a patient or withdrawn from it. Similarly, the biopsy cups 12 must reliably retain a sample obtained within them . There is however a space 21 formed between the biopsy cups 12 adjacent the end of the biopsy cups 12 closest to the pivotal point 16. Space 21 allows excess tissue to protrude from between from the biopsy cups 12 as the biopsy head 10 is closed around a tissue sample.

Actuator members 13 are connected to a suitable cable 36 shown in Figure 1. In the past cable 36 has typically comprised a metallic wire however the present invention optionally allows for the formation of an extruded plastic cable integral with actuator member 13. Cable 36 is sufficiently long to extend internally the length of an endoscope tube 38 wherein it is connected to a conventional actuator trigger 40. Endoscope tube 38 is connected at one end to actuator housing 34 of the biopsy head and at the other to handle 42. Accordingly by pushing actuator trigger 40 cable 36 is pushed towards pivot pin 30 and jaws 11 assume the configuration shown in Figure 4.

In use, biopsy head 10 is positioned adjacent the tissue to be sampled and the jaws opened as described. Cable 36 is then drawn backwards by the actuator device causing biopsy cups 12 to reverse their previous movement and to come together.

Any tissue caught between biopsy cups 12 will be sheared from the surrounding tissue by edges 18 as they are brought together.

The endoscope can then be withdrawn from the patient and the tissue sample recovered from the biopsy cups 12.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all aspects as illustrative and not restrictive.

Claims :

1. A biopsy device comprising :

a pair of biopsy jaws, each of said jaws having a tissue capturing means at a first end and a flexible joint at a second end, pivot engagement means being located between said first and second ends;

a pair of actuator members each coupled to one of said joints;

an actuator housing locating said actuator members;

a pivot means interconnecting said actuator housing and said pair of jaws;

each said biopsy jaw, including said flexible joint, being formed integrally with said actuator member.

2. A biopsy device according to claim 1, wherein said tissue capturing means are configured so that when said biopsy jaws are pivoted about said pivot means to a position where said cups abut each other there is a space between said biopsy cups proximal said pivot means.

3. A biopsy jaw and actuator means as specified in claim 1, said jaw and actuator means being formable in an injection moulding process.

4. An endoscopy device including a biopsy device according to claim 1.

5. A biopsy device according to claim 1 formed of nylon.

6. A biopsy device according to claim 1 or claim 5, wherein each of said jaws is formed by injection moulding.

7. A biopsy jaw forming one half of a pair of forceps for use in a biopsy device, said jaw including a flexible joint integrally connected to an actuator member.

8. A biopsy jaw according to claim 7 having tissue capturing means configured as a cup located at a position distal from said flexible joint.

9. A biopsy jaw according to claim 7 or 8 wherein said jaw and actuator means are formable by means of an injection moulding process.

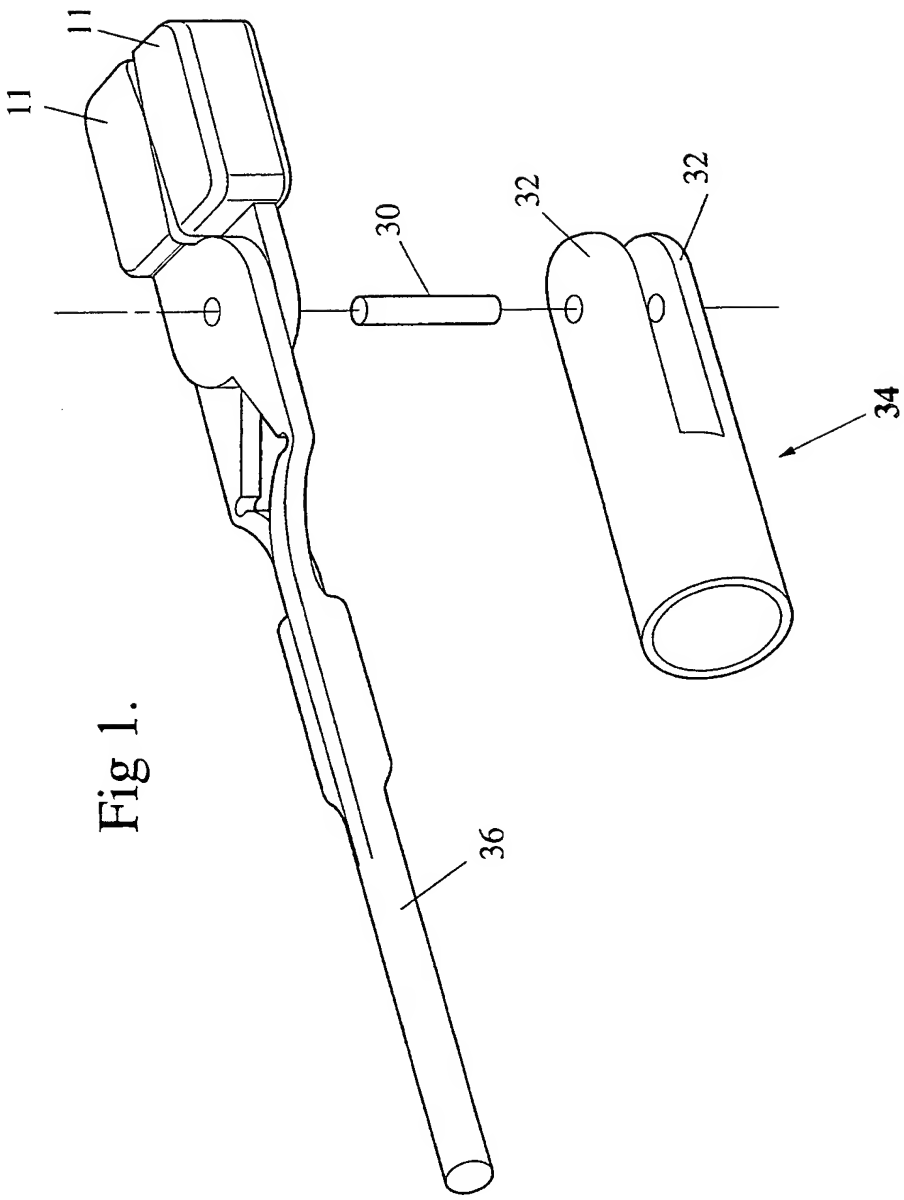


Fig 1.

Fig 2.

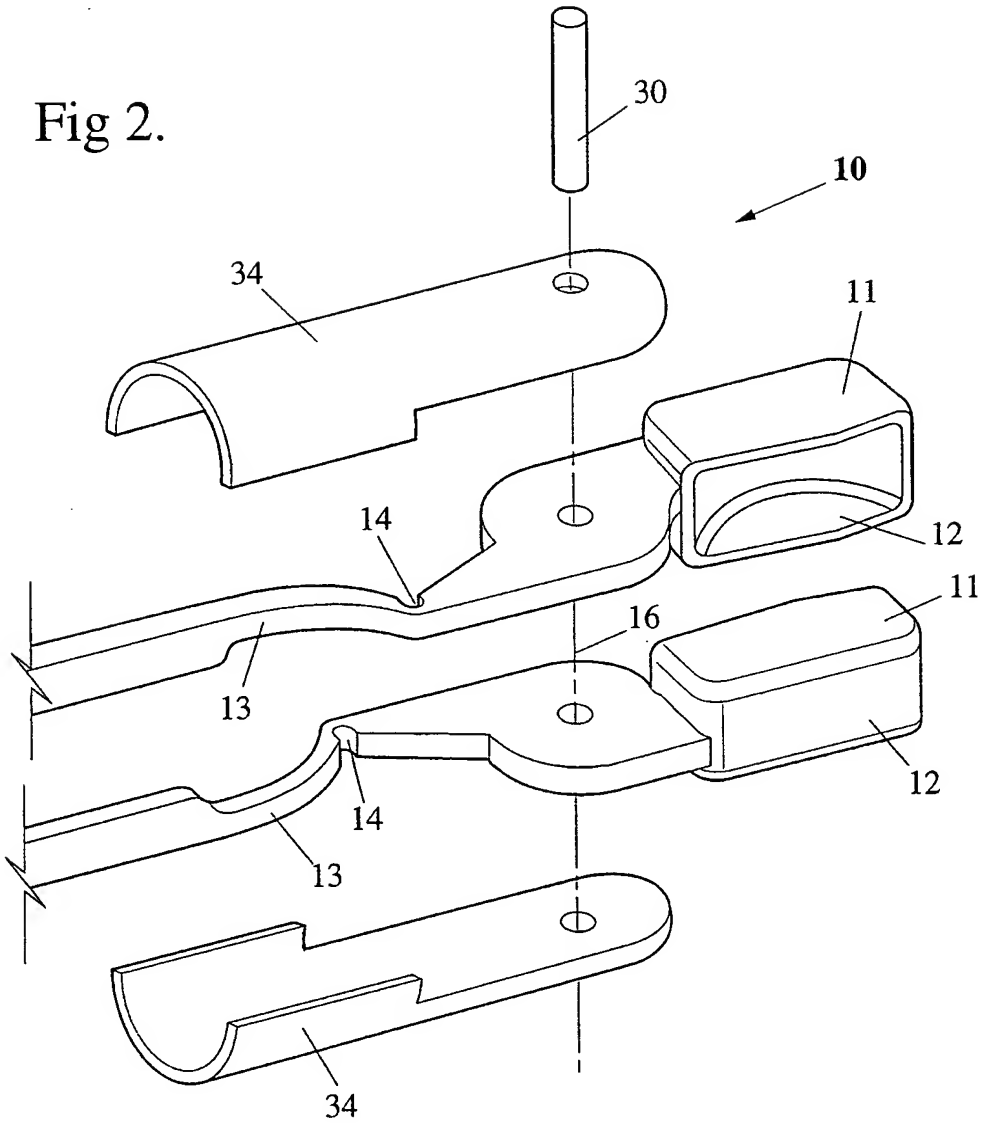


Fig 3.

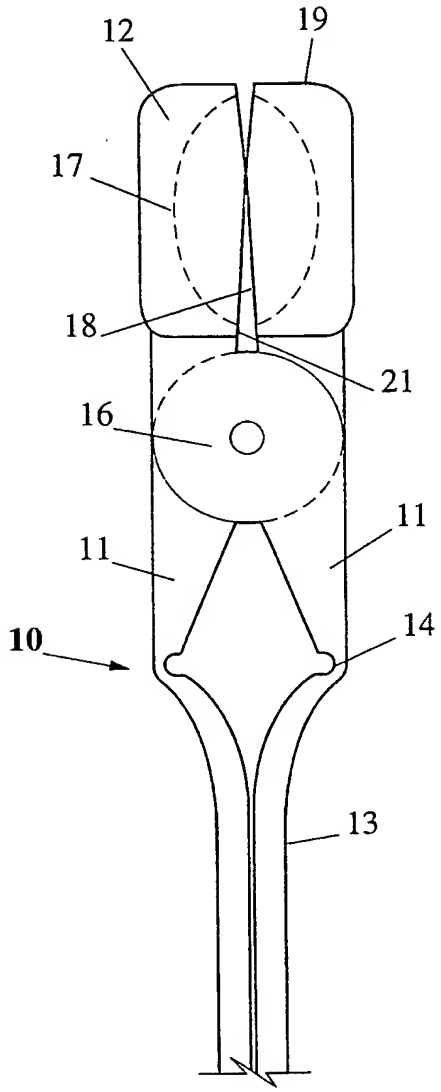
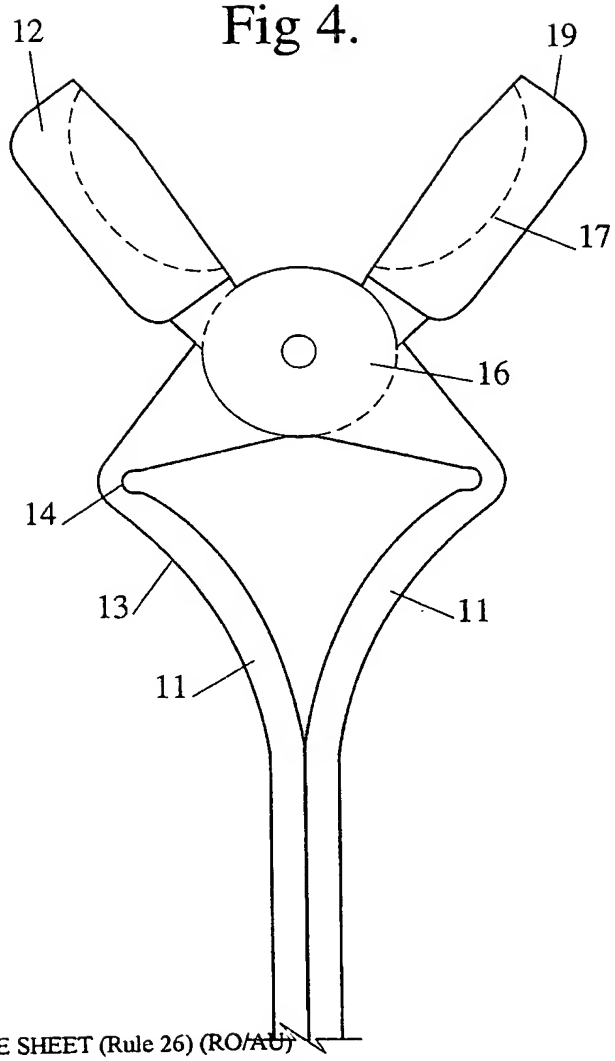


Fig 4.



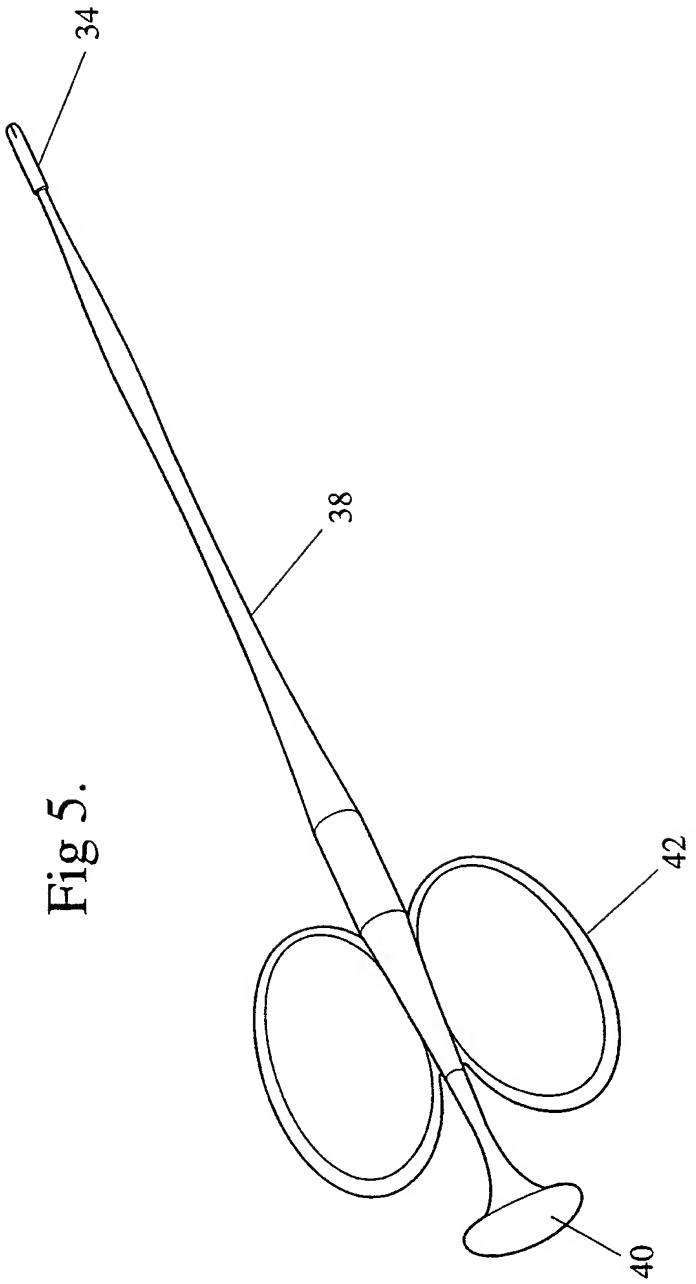


Fig 5.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00543

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU IPC : A61B 10/00 17/32

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT JAPIO ; forcep cup scissor jaw clamp pincer nylon plastic polymer flexible biopsy tissue mucus sample articulate joint hinge pivot link

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5172700 A (BENCINI et al) 22 December 1992 Column 7 lines 29 to 40, column 8 line 27 to column 9 line 45, figures 7 to 9	1 to 7
X Y	WO 95/08946 A (BOSTON SCIENTIFIC CORPORATION) 6 April 1995 Page 13 line 5 to page 14 line 30, figure 6	1 to 7 3,5,6
Y	EP 380874 A1 (C.R. BARD, INC) 8 August 1990 Column 7 line 30 to column 8 line 14, figure 5	3,5,6

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

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Date of the actual completion of the international search	Date of mailing of the international search report
18 August 1999	20 august 1999

Name and mailing address of the ISA/AU	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). **DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5238002 A (DEVLIN et al) 24 August 1993 Figure 7	1 to 7
Y	GB 1405889 A (IMPERIAL CHEMICAL INDUSTRIES LIMITED) 10 September 1975 Page 2 line 130 to page 3 line 3, figures 1 to 5	1 to 7
A	EP 611553 A2 (C.G.M. S.P.A.) 24 August 1994	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00543

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5172700	CA	2008190	EP	380874	US	5052402
WO	95/08946	CA	2172130	CA	2172132	CA	2172128
		CA	2172129	CA	2172131	EP	720440
		EP	720441	EP	720442	EP	720442
		EP	722286	EP	722287	WO	95/08291
		WO	95/08292	WO	95/08944	WO	95/08945
EP	380874	CA	2008190	US	5052402	US	5172700
US	5238002	CA	2097883	EP	573817	JP	06-030942
EP	611553	IT	1262303				

END OF ANNEX